Clinical Resources for the Microbiology and Infectious Diseases Research Community

Robert Johnson, PhD
Director, Office of Regulatory Affairs
Division of Microbiology and Infectious Diseases
NIAID, NIH, DHHS

December 10, 2012
Clinical Resources to Support Product Development

Product Development Pathway

- Basic Research
  - Hypothesis Development and Testing
- Preclinical Development
  - Discovery
  - IDE- and IND-Enabling Activities
- Clinical Evaluation
  - Trials

Research Tools and Technologies

- Clinical trials
- Support for clinical programs

Diagnostics
Vaccines
Therapeutics
Clinical Resources

- Broad programs
  - Phase I Clinical Trial Units
  - Vaccine and Therapeutic Evaluation Units (VTEUs)
- Ability to test different types of products:
  - Therapeutics
  - Vaccines
  - Devices
- Access to special populations
Vaccine and Treatment Evaluation Units and Phase I Clinical Trial Units
Clinical Resources

- Types of trials conducted include:
  - First in human
  - QTc trials
  - Trials with novel anti-microbial therapeutics
  - Multiple trials with biodefense agents including smallpox and anthrax vaccines
  - Flu vaccine trials in pediatric and elderly populations
Support for Clinical Evaluation

- Clinical Agents and Specimen Repository
- Clinical Research and Operations Management Support (CROMS)
- Regulatory Affairs Support
- Statistics and Data Coordinating Center for Clinical Research (SDCC)
Clinical Resources Eligibility Criteria

• Concept proposals may be submitted to the concept approval committee by
  – Investigational site Principal Investigators
  – DMID staff
Clinical Resources
Application Process

• Consultation with relevant Program Staff
  – Assessment of ‘readiness’
    • Availability of product for clinical use
    • Adequate non-clinical data available
  – Programmatic priorities
  – Budgetary constraints
  – Filling an important gap based in overall product development plan
Clinical Resources Approval Process

• Prioritized by DMID VTEU and Phase I Clinical Trials Concept Approval Committee based on:
  – Public health significance
  – Appropriateness and feasibility of study design
  – Capacity of proposed clinical sites
  – Proposed personnel
Clinical Resources
Assurances Provided

- Materials Transfer Agreement (MTA)
- Clinical Trial Agreement (CTA)
- Safety oversight, clinical monitoring, data management and regulatory management, as needed
Clinical Resources
Requirements for Users

• Clinical site investigators are expected to publish results:
  – Expectations and requirements detailed in CTA/MTA
• Manuscripts, abstracts and presentations provided to DMID and the company for review and comment prior to release
DMID Resources for Researchers

http://www3.niaid.nih.gov/LabsAndResources/resources/dmid/